Amendments To The Drawings:

Please amend Figure 7 by adding the reference numeral 26 to refer to the body portion. Support is found on page 20 at lines 17-23. No new matter has been added. A marked up copy and a clean copy are included herewith.

A new Figure 6a has been added to illustrate the tie layer 15 between balloon 20 and catheter shaft 25. This is supported at least from page 6, lines 1-3 of the specification and from claim 13 as originally filed. No new matter has been added.

Remarks

This Amendment is in response to the Office Action dated **December 28, 2007.** In Response to the Restriction Requirement Applicants elected Group I, claims 1-17, drawn to a dilatation balloon. Applicants have canceled claims 18-55 without prejudice and reserve the right to prosecute these claims in a divisional application.

Drawings

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the reference sign(s) mentioned in the description: 15 and 26.

The reference numeral 15 was a typographical error. It should be 22. Applicants have amended the paragraph on page 13, lines 32-34 to page 14, lines 1-2 to correct this. See paragraph on page 3, lines 20-22 and Fig. 3 wherein it is waist 22. No new matter has been added.

The reference numeral 26, referring to the body portion of the balloon (see page lines) was inadvertently excluded from Figure 7. Applicants have added reference numeral 26 to Figure 7 and have included marked up and clean copies. No new matter has been added.

The drawings are also objected to under 37 CFR 1.83(a) in paragraph no. 3 on page 2 of the Office Action. It is asserted that "[t]he drawings must show every feature of the invention specified in the claims. Therefore, the tie layer between the balloon and the catheter shaft must be shown or the feature(s) canceled from the claim(s)."

Applicant has added a new Figure 6a which is a radial cross-section showing balloon 20 mounted on catheter shaft 25 and a tie layer 15 therebetween. This is fully supported on page 6, lines 1-3 of the specification and from claim 13 as originally filed. No new matter has

been added.

Applicant has also added a description of Fig. 6a on page 9, line 32 under the BRIEF DESCRIPTION OF THE DRAWINGS, and on page 20 at line 17. No new matter has been added.

Applicants respectfully request withdrawal of the objection to the drawings.

Claim Objections

Claims 3-5, 7, 9 and 11-17 have been objected to because, it is asserted that:

> Claim 3 recites the limitation "said waist portions" in line 2. Claim 4 recites the limitation "said cone portions" in line 2. Claim 5 recites the limitation "said first layer" in lines 1-2. Claim 7 recites the limitation "said first layer" in line 1. Claim 9 recites the limitation "said second composition" in line 2. Claim 11 recites the limitation "said waist portion" in line 2. Claims 12 and 13 recite the limitation "said catheter shaft" in line 2. Claim 17 recites the limitation "said cone portion" in line 3. There is insufficient antecedent basis for these claims.

Office Action, pages 3-4, paragraph 4.

Applicants submit that claim 1, from which claim 3 depends, recited waist portions. However, for purposes of expediting prosecution, Applicants have amended claim 1 to further clarify "waist portions".

Applicants again submit that claim 1 does recite cone portions but for purposes of expediting prosecution, claim 1 has been amended for further clarification.

Claim 1 has also been amended to recite "first layer" and thus provide the proper antecedent basis for claims 5 and 7.

Claim 9 has been amended to recite "said second polymeric composition".

Claim 11 has been amended to recite "waist portions".

With respect to claims 12 and 13, claim 11 was amended to recite "catheter shaft"

which provide the proper antecedent basis for claims 12 and 13.

Claim 17 has been amended. Support is found at least from Fig. 6.

No new matter has been added.

Applicants respectfully request withdrawal of the claim objections.

Claim Rejections

35 U.S.C. §112

Claims 1-17 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is asserted that "[i]n claims 1 and 17, the use of a second layer is unclear as a first layer has not been established." Office Action, page 4, paragraph no. 6.

Claims 1 and 17 have been amended. No new matter has been added.

Applicants respectfully request withdrawal of the rejection of claims 1-17 under 35 U.S.C. §112, second paragraph.

35 U.S.C. §102(b)

Claims 1-6, 8, 11-13 and 17 have been rejected under 35 U.S.C. §102(b) as being anticipated by Kaneko et al. (U.S. Patent No. 5,344,400). It is asserted in the Office Action that

> Kaneko et al. disclose a dilatation balloon with a waist (10), cone, and body portions where the balloon is formed of a first polymeric composition (18) is formed on at least a portion of the balloon. The second layer comprises a second polymeric composition (16). Kaneko et al. disclose the second polymeric composition as a polyolefin. The polyolefin is capable of being crosslinked to form

a compression region....

Office action, pages 4-5, paragraph 8.

Applicants traverse the rejection.

Claim 1 of the present application is directed to an embodiment of a dilatation balloon formed of a first polymeric composition forming a first layer, and a second layer formed on at least a portion of the first layer that is crosslinked to form a compression region.

Kaneko et al. disclose "[a] balloon catheter having a balloon which is produced by molding polyarylenesulfide or an alloy thereof wherein polyarylenesulfide is a main constituent..." Abstract. The balloon may be fabricated by multi-layered extrusion molding using polyarylenesulfide, an alloy thereof, olefin polymer, an alloy thereof, and mixtures thereof. See for example, claim 2, and Background of the Invention.

Kaneko et al. is silent as to crossslinking the olefin polymer and is silent as to crosslinking any of the layers disclosed therein to form a compression region on a balloon.

Anticipation under 35 U.S.C. §102(b) requires that each and every claim element, as arranged in the claim, be disclosed by a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also MPEP 2131.

Kaneko et al. fail to disclose characterizing elements of claim 1, namely, the crosslinked polymeric layer for forming a compression region. Merely disclosing polymers that are <u>capable</u> of being crosslinked, contrary to the Office Action assertion, is not enough to anticipate the recitation in claim 1 of a crosslinked polymeric layer that forms a compression region.

Claims 2-16 depend from claim 1 and are not anticipated for at least the reasons

that claim 1 is not anticipated by Kaneko et al.

Claim 17 is directed to an embodiment of a dilatation balloon having among other features, waist, cone and body portions, a first balloon layer and a second balloon layer on at least one of the cone portions that is crosslinked to form a compression region

Claim 17 is not anticipated by Kaneko et al. for at least the reasons that claim 1 is not anticipated by Kaneko et al., and also, because Kaneko et al. is certainly silent as to forming a compression region on at least one cone by crosslinking a layer on at least the cone.

Applicants respectfully request withdrawal of the rejection of claims 1-17 under 35 U.S.C. §102(b) as anticipated by Kaneko et la.

35 U.S.C. §103(a)

Claims 7 and 9

Claims 7 and 9 have been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Dusbabek et al. (U.S. Patent No. 5,968,069).

It is asserted in the Office Action that:

> Kaneko et al. disclose the balloon substantially as claimed. Even though Kaneko et al. disclose the second composition as polyethylene (lines 47-53 of column 6), Kaneko et al. are silent on the first polymeric composition comprising a polyether block amide. Dusbabek et al. disclose a balloon where a first layer (214) comprising a first polymeric composition is formed of a polyether block amide and a second layer comprising a second polymeric composition (251). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use for the first polymeric composition of Kaneko et al. a polyether block amide as taught by Dusbabek et al. as both Kaneko et al. and Dusbabek et al. teach balloons with multiple layers and Dusbabek et al. teach that it is well known to use polyether block amide for the first layer.

Office Action, pages 5-6, paragraph 10.

Applicants traverse the rejection.

Claims 7 and 9 depend from claim 1.

Claim 1 has been discussed above and is directed to an embodiment of a *dilatation balloon* formed of a first polymeric layer and further including a second polymeric layer on at least a portion of the first polymeric layer to form a compression region.

As discussed above, Kaneko et al. is silent as to crosslinking polyethylene, and in fact is silent as to crosslinking any layer of the balloon disclosed therein so as to form compression regions on the balloon for improving tracking, cross and recross, and rewrap characteristics, for example. See page 3, last paragraph to page 4.

Dusbabek et al., contrary to what is asserted in the Office Action, is silent as to any multilayer construction, and is silent as to crosslinking any of the polymers disclosed for forming the balloon therein.

Furthermore, reference numeral (251) is actually employed by Dusbabek et al. to refer to sleeves or socks which are stretched over the ends of a stent, and are not actually crosslinked on the balloon to form a compression region. The description of FIGS. 34-36 of Dusbabek et al. make this clear:

> FIGS. 34 and 35 illustrate an alternative embodiment in which the tubing component is inflatable to increase the securement pressure on the inside of balloon 214 when the stent is crimped onto the balloon so as to negated additional recoiling. The full expansion of the tube component 216 should only be slightly greater than the diameter of the inside of the balloon 214 when the stent 218 is fully crimped onto the balloon 214.
>
> In FIG. 34, the inflating fluid comes through the guide wire lumen 212 under pressure from the proximal end or the distal end of the guide wire lumen 212, preferably via a syringe, and fills the tubing component 216 through a one-way valve 247 (preferably resisting up to about 4 atm) in the inner catheter 212.
>
> In FIG. 35, the tubing component 216 is inflated via an additional lumen 242

> which extends from the proximal end of the catheter along the guide wire lumen 240, much the same as any inflating lumen incorporated to inflate a balloon.
>
> In an alternative embodiment, as shown in FIG. 36, socks or sleeves 251 may be incorporated to stretch over the ends of the stent to prevent snagging and to secure the stent onto the balloon. Such sleeves are demonstrated in U.S. application Ser. Nos. 08/702,149, filed Aug. 23, 1996, and 08/701,979, filed Aug. 23, 1996, which are incorporated in their entirety herein by reference.

Column 19, lines 29-54.

Thus, the stent is crimped onto the balloon, and socks or sleeves are stretched over the ends of the stent, but are not on the balloon itself.

Therefore, the combination of Kaneko et al. and Dusbabek et al. neither discloses nor suggests characterizing elements of claim 1, namely, the crosslinked layer on at least a portion of a first balloon layer for forming a compression region on the balloon.

Claims 7 and 9 depend from claim 1 and are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination. Applicants respectfully request withdrawal of the rejection of claims 7 and 9 under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Dusbabek et al.

Claim 10

Claim 10 has been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Smith et al. (U.S. Patent No. 6,083,587). It is asserted in the Office Action that "…Kaneko et al. are silent on the specifics of the tie layer comprising polyethylene modified with at least one member. Smith et al. disclose multi-layered polymer structures for medical devices where a tie layer is formed between a first layer and a second layer….Smith et al. disclose the tie layer as comprising a polyethylene modified with maleic anhydride…"

Applicants traverse the rejection.

Claim 10 depends from claim 1.

As discussed above, Kaneko et al. fail to disclose a second polymeric layer over at least a portion of a first balloon polymeric layer that is crosslinked to form a region of compression on the balloon as recited in claim 1.

Combining the tie layer of Smith et al. fails to render claim 1 obvious.

Claim 10 is not obvious for at least the reasons that claim 1 is not obvious over Kaneko et al. in view of Smith. Applicants respectfully request withdrawal of the rejection of claim 10 under 35 U.S.C. §103(a).

Claims 14-18

Claims 14-16 have been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Branham et al. (U.S. Patent No. 6,897,168). It is asserted in the Office Action that "…Kaneko et al. are silent on the specifics of the tie layer comprising a crosslinking inhibitor or the tie layer being formed from a polymeric composition having a lower melting temperature that the first polymeric composition….Branham et al. disclose multilayered polymer structures for medical devices where a tie layer or a co-binder is formed between a first layer and second layer…comprising a crosslinking inhibitor and as having a lower melting temperature than the other layers…." Office Action, pages 6-7.

Applicants traverse the rejection.

Claims 14-16 depend from claim 1.

As discussed above, Kaneko et al. fail to disclose a crosslinked second polymeric layer over at least a portion of a first polymeric balloon layer which forms a compression region.

Combining the tie layer of Branham et al. with Kaneko et al. fails to render claim 1 obvious because the combination fails to disclose these characterizing features of claim 1.

Moreover, Branham et al. is directed to triggerable, water-dispersible, cationic polymers, methods of making them and their applicability as binder compositions. Branham et al. is further directed to fiber-containing fabrics and webs comprising triggerable, water-dispersible binder compositions and their use in water-dispersible personal care products such as wet wipes. Branham et al. is silent as to the polymer formulations disclosed therein being useful in making dilatation balloons for POBA (plain old balloon angioplasty) or for stent delivery:

> The polymer formulations of the present invention are particularly useful as a binder material for flushable personal care products, particularly wet wipes for personal use, such as cleaning or treating skin, make-up removal, nail polish removal, medical care, and also wipes for use in hard surface cleaning, automotive care, including wipes comprising cleaning agents, disinfectants, and the like…

Branham et al., Summary of the Invention, 2nd paragraph.

Applicants submit that common sense would dictate that one of ordinary skill in the art would not even look to nonanalogous art such as Branham et al. for modifying a medical dilatation balloon so as to improve balloon characteristics such as tracking, cross and recross, and rewrap. Even after *KSR*, there must be some reason to make the combination without the use of hindsight. See also *KSR International Co. v. Teleflex Inc.,* 82 USPQ2d 1385, 1396 (2007).

Even if, for the sake or argument only, Branham discloses polymers for a 'medical device' (i.e. wet wipes and the like), Branham cannot in any way be construed as being reasonably pertinent to solving problems of balloon deliverability and maneuverability within the vasculature of a patient:

> Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor,

> whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. In re Deminski, [796 F2D 436] 796 F.2d 436, 442, 230 USPQ 313, 315 (Fed.Cir. 1986); In re Wood, [599 F2D 1032] 599 F.2d 1032, 1036, 202 USPQ 171, 174 (CCPA 1979).

In re Clay, 23 USPQ2D 1058, 1060 (Fed. Cir. 1992).

For at least these reasons, claim 1 is not obvious over this combination, and claims 14-16 are not obvious over Kaneko et al. in view of Branham et al. for at least the reasons that claim 1 is not obvious over this combination. Applicants respectfully request withdrawal of the 35 U.S. C. §103(a) reject ion of claim 14-16.

CONCLUSION

Claims 1-17 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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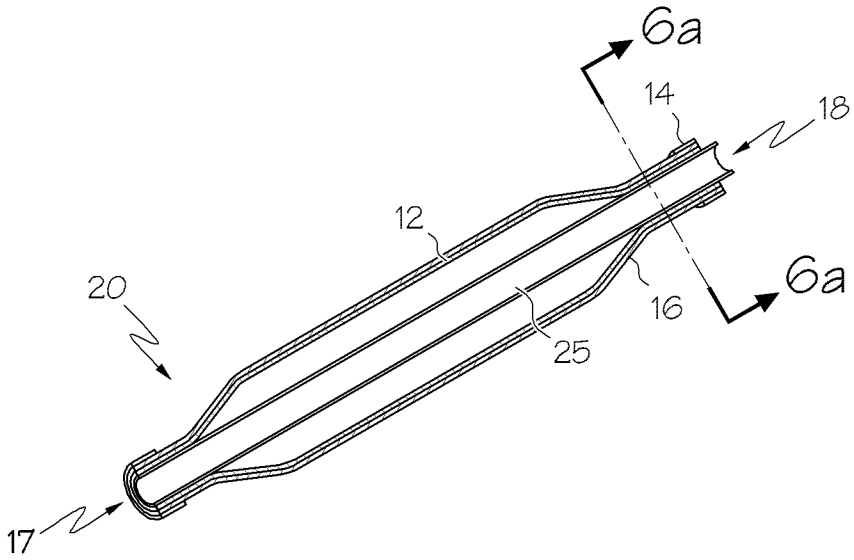

FIG. 6

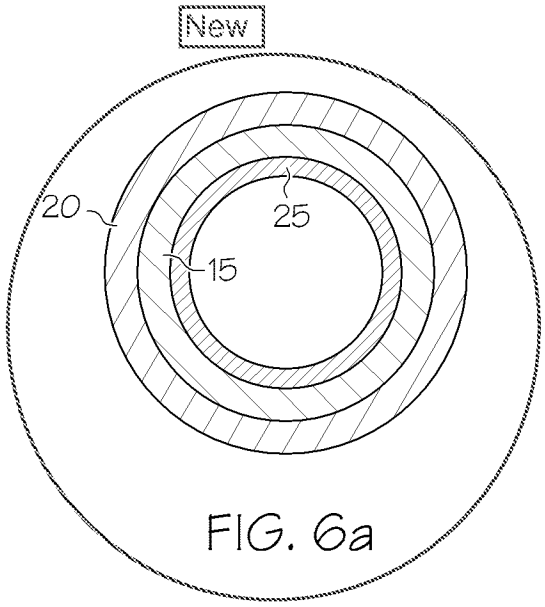

FIG. 6a

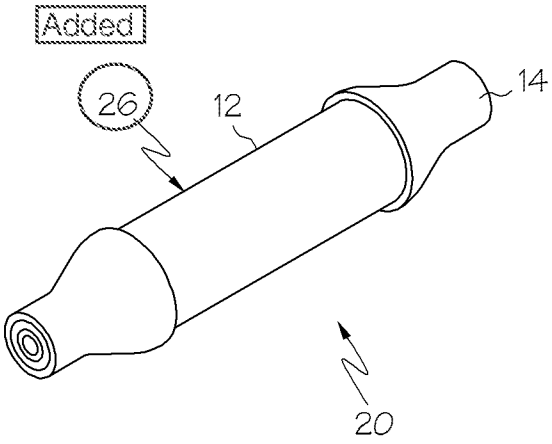

FIG. 7